510(k) Summary: JUL 1 2 2004 K041153

SharpsAway II™ Locking Disposal Cup

Submitter:	Arrow International Inc. 2400 Bernville Road Reading, PA 19605
Contact person:	Elizabeth Price Regulatory Associate Phone: 1-800-233-3187 Ext. 3220 Fax: (610)-478-3172 E-mail: Elizabeth.Price@arrowintl.com
Date summary prepared:	April 30, 2004
Date summary revised:	July 6, 2004
Device trade name:	SharpsAway II™ Locking Disposal Cup
Device common name:	Accessory to a Needle, Hypodermic, Single Lumen
Device classification name:	Needle, Hypodermic, Single Lumen
Legally marketed devices to which the device is substantially equivalent:	Devon Industries – Point-Lok® Neeedle Protection Device (K946289)
Description of device:	The proposed SharpsAway II™ Locking Disposal Cup was created to help prevent needle sticks by providing a means of moving used sharps from procedure to sharps container.
Intended use of the device:	The Arrow SharpsAway II™ Locking Disposal Cup is intended as a single use needle protection device, which covers the end of needles after use to minimize the risk of needle sticks. This device is designed for use with 15 Ga. to 30 Ga. needles for various clinical procedures.
Technological characteristics:	The technological characteristics are unchanged from the predicate device.

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Performance tests:	The following tests were performed to demonstrate substantial equivalence: • Simulated Use Study • Puncture Resistance • Gripping Mechanism Functionality Test • Water Leak
Conclusions:	The results of the performance tests demonstrate that the device is substantially equivalent to the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 2 2004

Ms. Elizabeth Price
Regulatory Affairs
Arrow International
2400 Bernville Road
Reading, Pennsylvania 19605

Re: K041153
Trade/Device Name: SharpsAway II ™ Locking Disposable Cup
Regulation Number: 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: April 30, 2004
Received: May 3, 2004

Dear Ms. Price:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

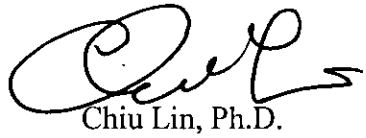
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K041153

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Prescription Use X AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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